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Section 5 – 510(k) Summary

Submitter:	St. Jude Medical - Atrial Fibrillation Division 14901 DeVeau Place Minnetonka, MN 55345 Establishment Registration Number: 2182269
Contact Person:	Joshua Clarin Regulatory Affairs Specialist Phone (651) 756-2855 Fax (952) 930-9481
Date Prepared:	June 25, 2008
Trade Name:	St. Jude Medical Epicardial Catheter System
Classification:	Class II - 21 CFR 870.1220 Electrode recording catheter or electrode recording probe Class II - 21 CFR 870.1340 Catheter Introducer
Product Code:	DRF DYB
Predicate Device(s):	The subject device is equivalent to the following St. Jude Medical devices: o Response™ Electrophysiology Catheter o Agilis™ NxT Steerable Introducer
Device Description:	The St. Jude Medical Epicardial Catheter System consists of the Response™ 6 French quadripolar electrophysiology catheter and the Agilis™ NxT 40 cm steerable guiding introducer (which includes a dilator, guidewire and steerable sheath). The Agilis NxT Steerable Introducer provides pericardial access for the Response catheter to perform electrophysiology studies of the epicardial surface of the heart.
Intended Use:	The St. Jude Medical Epicardial Catheter System is intended for electrophysiology studies involving the epicardial surface of the heart.
Comparison to Predicate Devices	The St. Jude Medical Epicardial Catheter System has a similar intended use and the same fundamental scientific technology as the predicate devices. All technological characteristics of the of the Epicardial Catheter System are substantially equivalent to the predicate devices including packaging, biocompatibility, sterilization, and labeling. Where differences exist between the proposed devices and the predicate devices, performance testing demonstrated that these differences do not adversely affect the safety and effectiveness of the proposed devices.
Conclusion:	St. Jude Medical considers the Epicardial Catheter System to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in design, technological characteristics, principles of operation, materials, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 13 2009

St. Jude Medical
c/o Mr. Joshua Clarin
Regulatory Affair Specialist
One St. Jude Medical Drive
St. Paul, MN 55117

Re: K081803
Trade/Device Name: Epicardial Catheter System
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter
Regulatory Class: Class II (two)
Product Code: DRF
Dated: April 17, 2009
Received: April 20, 2009

Dear Mr. Clarin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081803

Device Name: St Jude Medical Epicardial Catheter System

Indications for Use:

The St. Jude Medical Epicardial Catheter System is intended for electrophysiology studies involving the epicardial surface of the heart.

Prescription Use __X__ AND/OR Over-The-Counter Use ____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K081803